

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

BAUSCH HEALTH
IRELAND LIMITED, et al.,

Plaintiffs,

v.

PADAGIS ISRAEL
PHARMACEUTICALS LTD et al.,

Defendants.

**Civil Action No. 20-5426 (SRC)
(CONSOLIDATED)**

OPINION & ORDER

CHESLER, U.S.D.J.

This matter comes before the Court on the motion for summary judgment of no inequitable conduct by Plaintiffs Bausch Health Ireland Limited, Bausch Health Americas Inc., and Bausch Health US, LLC (collectively, “Bausch”). The motion is opposed by Defendants Padagis Israel Pharmaceuticals LTD and Padagis US LLC (collectively, “Padagis.”) This motion concerns patents related to the drug Duobrii®. Padagis is a pharmaceutical company which has filed ANDA No. 214626 to produce a generic version of that pharmaceutical product. Bausch owns U.S. Patent Nos. 10,251,895 (“the ’895 patent”) and 10,426,787 (the “’787 patent,” and together with the ’895 patent, the “Combination Patents”). For the reasons that follow, Plaintiffs’ motion will be granted.

United States Patent Application No. 15/173,961 ultimately issued as the ’895 patent. United States Patent Application No. 15/903,785 ultimately issued as the ’787 patent. The Combination Patents have the same inventors, both claim priority to United States Provisional

Patent Application No. 15/903,785, which was filed on June 18, 2015, and the two patents have substantially identical specifications, for purposes of this motion. In briefing this motion, the parties have generally treated the two prosecution histories as if they were the same and have not pointed to any material differences between the actions of the applicants or the PTO in the two prosecution histories. The parties do not dispute that the statements of the reasons for allowance issued by the Examiner in the two prosecutions are nearly identical. Because, in briefing this motion, the parties have generally treated the two prosecution histories as not differing materially, this Court follows suit. In this Opinion, the Court will generally cite to the prosecution history of the ‘895 patent, with the understanding that a parallel citation to the prosecution history of the ‘787 patent is implied.

LEGAL STANDARD

Summary judgment is appropriate under FED. R. CIV. P. 56(a) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party’s entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). “In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence ‘is to be believed and all justifiable inferences are to be drawn in his favor.’” Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

“When the moving party has the burden of proof at trial, that party must show

affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party.” In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). “[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by ‘showing’ – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party’s case.” Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). “[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment.” Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). “A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial.”¹ Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001). “In reviewing the

¹ Both parties’ briefs refer to a jury as factfinder at trial. “Inequitable conduct is equitable in nature, with no right to a jury, and the trial court has the obligation to resolve the underlying facts of materiality and intent.” Am. Calcar, Inc. v. Am. Honda Motor Co., 651 F.3d 1318, 1333 (Fed. Cir. 2011). While a court sitting in equity may allow a jury trial, the jury verdict is advisory and does not bind the court. Id. at 1334. It is this Court that serves as factfinder at a trial of an inequitable conduct claim.

record, the court must give the nonmoving party the benefit of all reasonable inferences.”

Brewer v. Quaker State Oil Ref. Corp., 72 F.3d 326, 330 (3d Cir. 1995).

If the nonmoving party has failed “to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial, . . . there can be ‘no genuine issue of material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 n.5 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

DISCUSSION

I. The motion for partial summary judgment

Bausch moves for summary judgment on Padagis’ affirmative defense and counterclaim that the ’895 patent and the ’787 patent are unenforceable due to inequitable conduct. As the movant without the burden of proof at trial, Bausch meets its initial summary judgment burden by pointing to the absence of evidence to support Padagis’ inequitable conduct case. The summary judgment burden then shifts to Padagis.

The parties agree that the Federal Circuit set forth the basic principles of the contemporary law of inequitable conduct in Therasense:

[I]nequitable conduct came to require a finding of both intent to deceive and materiality. To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. If the accused infringer meets its burden, then the district court must weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable.

Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011) (citations

omitted).

Padagis asserts two theories of inequitable conduct during prosecution of the Combination Patents. First, Padagis asserts that “[t]he record in this case provides clear and convincing evidence that Dr. Sugarman submitted false declarations during prosecution of the Combination Patents and did so with specific intent to deceive the USPTO” (hereinafter, the “Sugarman Theory.”) (Defs.’ Opp. Br. at 16.) Second, Padagis asserts that “[t]he record provides clear and convincing evidence that at least Dr. Pillai, a named inventor, knowingly withheld material prior art during prosecution of the Combination Patents with intent to deceive the USPTO” (hereinafter, the “Pillai Theory.”) (Defs.’ Opp. Br. at 30.)

A. The Sugarman Theory

1. Material falseness

As to the Sugarman Theory, Padagis argues that the Sugarman Declaration, filed by the applicants during prosecution of both patents, is materially false, as it contains the following materially false statement in paragraph 11: “the Invention unexpectedly achieved the synergistic efficacy over the combination of halobetasol propionate and tazarotene monotherapies” (hereinafter, the “Alleged False Statement.”) Padagis contends that the word “unexpectedly” in that statement is a falsehood, and that Sugarman knew that synergistic efficacy was expected when he wrote that statement in 2018. As evidence, Padagis principally² relies on a 2017

² Defendants’ opposition brief also offers one sentence which asserts that skilled artisans, before the filing date of the Combination Patents, “recognized the potential for synergistic efficacy from the combination of tazarotene and mid- to high-potency topical corticosteroids, such as halobetasol propionate.” (Defs.’ Opp. Br. at 17.) In support of that assertion, the opposition brief cites paragraphs in Defendants’ responsive Rule 56.1 statement that do not address the knowledge of skilled artisans prior to the filing date on this subject.

publication, a research article on which Sugarman is the first named author, published in 2017 in the Journal of Drugs in Dermatology (“Sugarman 2017.”) (Bruno Dec. Ex. 30.) Padagis points to a sentence in this publication which states: “combining a topical corticosteroid [with tazarotene] is one option that may prevent the irritancy effects of tazarotene while providing a synergistic therapeutic effect as well as a potential decrease in steroid-induced atrophy” (hereinafter, the “2017 Statement.”) (Id. at 198.)

Padagis summarizes its argument for the falsity of the Alleged False Statement as follows: “Padagis’s Opposition repeatedly identified Dr. Sugarman’s statement that the invention ‘unexpectedly achieved synergistic efficacy’ as being false and directly contradicted by his statement in Sugarman 2017.”³ (Def.’s Sur-Reply Br. at 2 n.2.) Thus, Defendants’ principal evidence of the falsity of the Alleged False Statement is the statement in Sugarman 2017 which, Padagis argues, directly contradicts the Alleged False Statement. At this stage in the summary judgment analysis, to defeat the motion for summary judgment as to the Sugarman Theory, Padagis must provide sufficient evidence to allow a factfinder to find in its favor at trial.

The key question is, then: has Padagis offered sufficient evidence to allow a factfinder to find, at trial, that the 2017 Statement directly contradicts the Alleged False Statement? Padagis offers the evidence of the two documents themselves, the Sugarman Declaration and the Sugarman 2017 publication, and argues that a direct contradiction is demonstrated by comparing the Alleged False Statement in the Sugarman Declaration, which bears a signature date of July

³ Similarly: “This direct conflict between Dr. Sugarman’s own statements is affirmative evidence that the Sugarman Declaration was false” (Defs.’ Sur-Reply Br. at 6.); “the falsity of Dr. Sugarman’s declaration is evidenced by his own contradictory statements in a peer-reviewed scientific article” (Defs.’ Opp. Br. at 29.)

23, 2018, with the “2017 Statement,”⁴ which bears a journal issue date of March, 2017. Padagis argues that the 2017 Statement constitutes evidence that the word “unexpectedly” in the Alleged False Statement is false, and that the 2017 Statement shows that such synergistic therapeutic effect from the combination of Taz and corticosteroids was a phenomenon known to the art in 2015, and therefore not unexpected.

First, the Court considers the Sugarman Declaration and the Alleged False Statement. Padagis states: “The most reasonable interpretation of the Sugarman Declaration is that the statements were made from the perspective of a skilled artisan as of the effective filing date, June 18, 2015.” (Defs.’ Opp. Br. at 17 n.5.) The Court agrees that the evidence supports the inference that the Alleged False Statement was written from the perspective of a time frame before the art learned about the invention. Consider the Alleged False Statement (*italicized*) in the context of the surrounding paragraphs:

10. Thus, although potent corticosteroids and tazarotene have been used or attempted for the treatment of psoriasis, they had not been shown to be effective at low concentrations at the time of the Invention. In fact, at the time of the Invention, people of ordinary skill in the art did not believe that the combination of a low concentration of halobetasol propionate and a low concentration of tazarotene would be effective for treating psoriasis. Prior to the Invention, clinical practice in topical treatment of psoriasis was to use the most potent drugs at the highest tolerable strength.

11. I was very surprised when the applicants showed the results of the clinical trials of the Invention to me. As summarized in Tables 7 and 8 of the specification, *the Invention unexpectedly achieved the synergistic efficacy over the combination of halobetasol propionate and tazarotene monotherapies.*

12. In addition, although corticosteroids have been observed to reduce the severity of skin reactions when used in conjunction with tazarotene, people of ordinary skill in the art expected that such benefit required much higher corticosteroid concentrations than that of halobetasol propionate in the Invention. The only FDA

⁴ Padagis refers to the 2017 Statement as the “synergy statement.”

approved concentration of halobetasol propionate is 0.05%, which is 5 times more than the halobetasol propionate content of the Invention. Therefore, I was surprised to see that a low concentration of 0.01% halobetasol propionate could be enough to significantly reduce the side effects of tazarotene monotherapy, as reported in Table 13 of the specification.

(Bruno Dec. Ex. 10 at 2-3.) Paragraph 10 clearly locates a time frame of interest, the time before the invention was disclosed or known to the art: “Prior to the Invention” (hereinafter, the “Time Before the Invention Was Public.”) Paragraph 11 clearly locates a time frame of interest: “when the applicants showed the results of the clinical trials of the Invention to me.” Paragraph 11 states that Sugarman felt surprise at that time (hereinafter, the “Time of Surprise.”) Paragraph 12 coordinates the Time Before the Invention Was Public and the Time of Surprise. Paragraph 12 explains that Sugarman felt surprise at the Time of Surprise because, prior to his being shown the results, as referenced in Paragraph 11, he had had the knowledge typical of the skilled artisan during the Time Before the Invention Was Public. Therefore, these paragraphs of the Sugarman Declaration inform the reader that the Time of Surprise occurred during the time that Sugarman and others in the art did not know about the invention. A reasonable factfinder would make such an inference about the time frame of the Alleged False Statement. This is consistent with Defendants’ contention that the most reasonable interpretation of the Sugarman Declaration is that the statements were made from the perspective of a skilled artisan as of the effective filing date. Padagis does not argue that one can reasonably interpret the time frame of the Sugarman Declaration to reach any other result.

Next, the Court considers Sugarman 2017, which is titled, “A Phase 2, Multicenter, Double-Blind, Randomized, Vehicle Controlled Study to Assess the Safety and Efficacy of a Halobetasol/Tazarotene Fixed Combination in the Treatment of Plaque Psoriasis.” (Bruno Dec.

Ex. 30 at 197.) The publication lists Sugarman as the first author, with five other co-authors.

(Id.) The following quote shows the 2017 Statement in context (italics added):

Tazarotene has been shown to be an effective treatment for psoriasis. Use of topical tazarotene is limited by its potential irritancy. However, *combining a topical corticosteroid is one option that may prevent the irritancy effects of tazarotene while providing a synergistic therapeutic effect as well as a potential decrease in steroid-induced atrophy.*

The combination of tazarotene and either mid- or high-potency topical corticosteroid has been shown to be more effective than therapy with tazarotene alone; however, it has not determined if tazarotene plus topical steroid was superior to topical corticosteroid alone.

The objective of our study was to investigate the efficacy and safety of a once-daily application of a fixed combination halobetasol propionate 0.01% and tazarotene 0.045% (HP/TAZ) lotion in comparison with its monads (HP and TAZ), and vehicle in subjects with moderate-to-severe plaque psoriasis.

(Bruno Dec. Ex. 30 at 197-98.) There is no dispute that the 2017 Statement bears a publication date of March, 2017.

Padagis argues: “The record as a whole supports the conclusion that the synergy statement in Sugarman 2017 reflects the knowledge of those skilled in the art that existed before the 201 Study and before the effective filing date of the Combination Patents.” (Defs.’ Opp. Br. at 20.) Thus, Padagis contends that the 2017 Statement states a historical fact about the knowledge of the art before June of 2015, the filing date.

In short, this Court finds that Sugarman 2017 contains no evidence from which a reasonable factfinder could conclude that the 2017 Statement states a historical fact about the knowledge of the art before June of 2015, the filing date. From the outset, the key problem for Padagis is that the 2017 Statement does not appear to be an assertion of any pre-existing, historical fact. It is, instead, a statement about a present option joined with a statement of

contingency, possibility, or potential. Note the verb forms (*italics added*):

However, combining a topical corticosteroid *is* one option that *may prevent* the irritancy effects of tazarotene while providing a synergistic therapeutic effect as well as a potential decrease in steroid-induced atrophy.⁵

The sentence says that combining Taz with a topical corticosteroid “is” one option; this is present tense, and so combining the two components is presently one option, most likely from the perspective of the skilled artisan at the time of publication, in March of 2017.⁶ The verb clause “may prevent” appears to be the form expressing possibility or potential: the combination option has the potential to provide a synergistic therapeutic effect, and also has the potential to decrease steroid-induced atrophy. The use of the word “potential” in the sentence provides further support for the interpretation that the effects are potential ones. There does not appear to be more meaning that can be extracted from this sentence. The sentence does not appear to state any pre-existing historical facts, but asserts only a present option with the possibility of/potential for (un)certain effects. The fact that the sentence ends with a footnote to a 2001 publication does not convert the text into a statement about the knowledge of the art in 2015. Padagis has pointed to no word or words in the sentence that refer to 2015 or link the sentence to the knowledge of the art prior to the filing date of the Combination Patents.

One could quite reasonably ask, why did the authors of Sugarman 2017 think that

⁵ The 2017 Statement ends with a footnote to a reference, the Kaidbey 2001 reference. Padagis does not contend that Kaidbey 2001 discloses synergistic efficacy of a combination therapy. Rather, Padagis states that Kaidbey 2001 “primarily concerns . . . reduction in steroid-induced atrophy.” (Def.’s Sur-Reply Br. at 8.) The presence of the footnote to Kaidbey 2001 does not provide any evidence relevant to the question presently before the Court. If anything, it might be noteworthy that there is no footnote to any publication about synergistic therapeutic effect.

⁶ While combining Taz and a corticosteroid is a present option, the sentence does not provide any information about when the art discovered that option.

combining Taz and a topical corticosteroid *might* have these effects? The text before this Court does not, however, provide any answers to that question, which is tangential to the question before this Court. It is enough to determine that there is no evidence within the sentence itself that it is an assertion about the state of something in 2015. Instead, the 2017 Statement appears to express an idea about the present (combining *is* an option) and some ideas about potential effects of using that option.

The Court is not persuaded by Defendants' arguments to the contrary. In short, Padagis points to nothing within the publication that links the 2017 Statement with the knowledge of the prior art in 2015, nor anything extrinsic to the publication that appears both relevant to and informative about the issue at hand. Moreover, the interpretation that Padagis proposes – an assertion of historical fact about the time before June of 2015 – appears contrary to the plain meaning of the language in the sentence, which refers both to a present option and what its effects *may* be.

Padagis argues that there is evidence to support the inference that the 2017 Statement refers to the timeframe of June, 2015 and before. Padagis first vaguely contends that the surrounding textual context of the 2017 Statement is meaningful, as it appears in a discussion generally about what was known in the art. The Court agrees that the 2017 Statement appears in the context of other statements about what has been known in the art, but this does not support Defendants' very specific hypothesis that the 2017 Statement states a historical fact about the knowledge of the art prior to June of 2015.

Defendants' other arguments about the timeframe of the 2017 Statement do not support their very specific hypothesis that it refers to what was known in the art prior to June of 2015.

Defendants point to similarities to statements in documents that bear a pre-filing date (e.g., Def.'s Supp. 56.1 Stmt. ¶¶ 36, 37, 38), and attempt to cast doubt on the veracity of other statements made by Sugarman in other settings.⁷ Padagis does not, however, offer any evidence from which a reasonable factfinder could conclude that the 2017 Statement means what Padagis argues it means, that it teaches that the synergistic efficacy of the combined therapy was known to the art before the filing date in 2015.

The result of this analysis is that this Court finds no contradiction: nothing in the 2017 Statement contradicts the Alleged False Statement or is evidence of its falsity. Padagis has offered no evidence from which a reasonable factfinder could conclude that Sugarman's Alleged False Statement, asserting that the invention unexpectedly achieved synergistic efficacy, is false. As to material falseness, the Court finds that the 2017 Statement does not constitute "sufficient evidence to allow a jury to find in its favor at trial." Gleason, 243 F.3d at 138.

2. Intent to deceive the PTO

The second element of the Sugarman Theory inequitable conduct case concerns the question of whether Sugarman intended to deceive the PTO by submitting the 2017 Declaration. The Federal Circuit has held:

Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. However, to meet the clear and convincing evidence standard, the specific intent to deceive must be "the single most reasonable inference able to be drawn from the evidence." Indeed, the evidence "must be sufficient to require a finding of deceitful intent in the light of all the circumstances." Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found.

⁷ The general credibility of Dr. Sugarman's testimony as a witness is not relevant to the inquiry into the meaning of a sentence in a publication with multiple authors.

Therasense, 649 F.3d at 1290-91 (citations omitted). Padagis argues that “[t]he single most reasonable inference from the evidence is that Dr. Sugarman . . . submitted the declarations with the intent to deceive the USPTO.” (Def.’s Opp. Br. at 23.) Padagis again relies primarily on Sugarman 2017: “This discrepancy between the state of the art described in the Introduction of Sugarman 2017 (Dr. Sugarman’s own article) and his subsequent representations to the USPTO in the Sugarman Declaration is sufficient on its own to support the inference that Dr. Sugarman intended to deceive the USPTO.” (Def.’s Opp. Br. at 24.) Padagis makes clear that this is the same theory of direct contradiction that has already been discussed: “the Sugarman Declaration included affirmative misrepresentations that directly conflicted with his own prior statements in a peer-reviewed scientific publication on the same subject matter.” (Def.’s Opp. Br. at 28.)

“[A] court must weigh the evidence of intent to deceive independent of its analysis of materiality.” Therasense, 649 F.3d at 1290. As already explained, no reasonable finder of fact could hear the evidence of record and conclude that the statements of interest in Sugarman 2017 directly conflict with, or contradict, the Alleged False Statement. Absent a demonstration of such a conflict, no reasonable finder of fact could consider the evidence in Sugarman 2017 and conclude that either Sugarman or the applicants intended to deceive the PTO by submitting the 2017 Declaration. Nor does the other evidence of record cited by Padagis (see Def.’s Supp. 56.1 Stmt. ¶¶ 56, 57, 58) provide a sufficient basis for a finding that the single most reasonable inference is that Sugarman intended to deceive the PTO. As to the element of intent to deceive the PTO, Padagis has failed to offer evidence sufficient to allow a jury to find in its favor at trial.

To support its case, Padagis cites Lipman v. Dickinson, 174 F.3d 1363, 1370 (Fed. Cir. 1999): “The fact of misrepresentation coupled with proof that the party making it had knowledge

of its falsity is enough to warrant drawing the inference that there was a fraudulent intent.” This is on point, and this Court finds that Padagis has failed to offer sufficient evidence to support a finding of fact that the Alleged False Statement contained a misrepresentation or that Sugarman had knowledge that the Alleged False Statement was false, based on the evidence cited by Padagis.

Padagis criticizes Bausch’s argument that Sugarman’s lack of deceptive intent is evidenced by his deposition testimony, and Padagis argues that such testimony raises a question of credibility that cannot be resolved on summary judgment. As already stated, Sugarman’s credibility as a witness is not at issue here: Defendants’ inequitable conduct case rests principally on the question of whether there is a conflict or contradiction between statements in two documents, one of which had multiple authors.

Padagis has failed to persuade this Court that an intent to deceive on Sugarman’s part is a reasonable inference based on the evidence of record, much less the single most reasonable inference to be drawn from the evidence. The Federal Circuit has cautioned that “[t]he intent requirement is demanding.” Intercontinental Great Brands LLC v. Kellogg N. Am. Co., 869 F.3d 1336, 1351 (Fed. Cir. 2017). Here, Padagis has pointed to no evidence which supports a finding that Sugarman intended to deceive the PTO. No reasonable jury could conclude that the single most reasonable inference to be drawn from the evidence is that Sugarman intended to deceive the PTO when he made the Alleged False Statement.

As to the Sugarman Theory of inequitable conduct, Padagis has failed to defeat Plaintiff’s motion for summary judgment of no inequitable conduct.

B. The Pillai Theory

As to the Pillai Theory, Padagis contends that “[t]he record provides clear and convincing evidence that at least Dr. Pillai, a named inventor of the Combination Patents, knowingly withheld material prior art during prosecution of the Combination Patents with intent to deceive the USPTO.” (Defs.’ Opp. Br. at 30.) Padagis alleges that Pillai withheld the posting of Study No. NCT02045277 on the website, ClinicalTrials.Gov (hereinafter, the “Posting.”) There is no dispute over certain basic facts. Bausch registered the study on the website on January 22, 2014, and submitted three revisions to the Posting in 2014. The Posting disclosed the use of IDP-118 lotion for the treatment of plaque psoriasis. The 2014 Postings disclosed that IDP-118 lotion comprises active ingredients halobetasol propionate (“HP”) 0.01% and tazarotene (“Taz”) 0.045%. The Postings were publicly available, and continue to be so. The applicants did not disclose the Posting to the PTO as prior art during prosecution of the Combination Patents. The first three versions of the Posting were publicly disclosed more than one year before the priority date of the Combination patents, June 18, 2015. For the purpose of this motion, Bausch does not dispute that the Postings constitute prior art.

As to the Pillai Theory, Bausch moves for summary judgment of no inequitable conduct on the ground that Padagis lacks sufficient evidence to demonstrate any of the three elements needed to prove inequitable conduct: “the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” Therasense, 649 F.3d at 1290. As the movant which does not bear the burden of proof of inequitable conduct at trial, Bausch satisfies its initial summary judgment burden by pointing out the absence of evidence to support the non-movant’s case.

The summary judgment burden then shifts to Padagis, which must provide sufficient evidence to allow a finding in its favor at trial.

Padagis contends that the evidence shows that the Posting was a material prior art reference. The Federal Circuit applies the following principles to the materiality inquiry, in the context of an inequitable conduct claim:

As a general matter, the materiality required to establish inequitable conduct is but-for materiality. A prior art reference is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. In determining the materiality of a reference, the court applies the preponderance of the evidence standard and gives claims their broadest reasonable construction.

A reference is not but-for material, however, if it is merely cumulative. A reference is cumulative when it teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO.

...

Determining but-for materiality requires that the court place itself in the shoes of a patent examiner and determine whether, had the reference(s) been before the examiner at the time, the claims of the patent would have still issued. . . . [T]he court must determine whether a reasonable patent examiner would have allowed the claims had she known of the Withheld References.

Regeneron Pharm., Inc. v. Merus N.V., 864 F.3d 1343, 1350-51 (Fed. Cir. 2017) (citations omitted.)

Defendant presents the core of its materiality argument in one paragraph:

The Examiner's Reasons for Allowance for both patents further demonstrate the critical importance the Examiner placed on the claimed drug concentrations in allowing the claims. The Examiner emphasized that the prior art did not teach or suggest the claimed synergy limitations for a composition comprising halobetasol propionate and tazarotene ***at the claimed concentrations***. Padagis SMF ¶ 87. The Examiner specifically noted that Gandhi, the closest prior art of record, disclosed the combination of halobetasol propionate and tazarotene in a single formulation, but that it did "not suggest a synergism between halobetasol-propionate and tazarotene at the doses above, ***nor at the claimed amounts of each agent***." Padagis SMF ¶ 88. Accordingly, the record evidence demonstrates that the claimed concentrations of halobetasol propionate and tazarotene in a single lotion were critical to the issuance of the Combination Patents. See Padagis SMF ¶¶ 83-

91. Therefore, it is more likely than not that the Examiner would not have allowed the claims had he been aware of the CT.Gov Study Record's disclosure of the exact concentrations claimed in a single lotion to treat psoriasis.

(Def.'s Opp. Br. at 32.) In addition, Padagis likens this situation to that in Belcher Pharm., LLC v. Hospira, Inc., 11 F.4th 1345, 1353 (Fed. Cir. 2021), arguing:

Bausch's "alleged critical improvement over the prior art was therefore already within the public domain, just not before the examiner." *See Belcher*, 11 F.4th at 1353. Accordingly, the claims of the Combination Patents would not have issued **but for** the withholding of CT.Gov Study Record.

(Def.'s Opp. Br. at 33-34.)

As already explained, in this Opinion, the Court will refer to the prosecution history of one of the two patents at issue, the '895 patent, and will discuss documents from the file wrapper of application 15/173,961, which matured into the '895 patent; the parties do not contend that the prosecution history of the '787 patent differs materially for the purpose of this motion. The Court begins its close examination of the prosecution history at the date of December 28, 2017, when the PTO issued a non-final rejection of all pending claims. (Bruno Dec. Ex. 19.) The Examiner's explanation stated, *inter alia*, that the pending claims were rejected as obvious over the combination of Gandhi, Angel, Bershad, and Jackson. (*Id.* at 5.) Over the course of pages 13 through 18, the Examiner explained, in detail and at length, the reasoning supporting this analysis, and the reasons for rejecting the applicants' arguments submitted to overcome the previous obviousness rejection.⁸ The Examiner began the explanation of the obviousness analysis by stating:

37. Applicant's amendments, filed 10/11/2017 are acknowledged and have been carefully considered but remain unpersuasive. In regards to Applicants contention

⁸ Prior to December 28, 2017, there had already been two Office Actions containing claim rejections, and two responsive submissions from the applicants.

that the combination of Jackson and Angel fail to cure the deficiencies of Gandhi, the Examiner acknowledges and does not dispute Applicants contention that Gandhi does not explicitly teach the combination of 0.01% wt. halobetasol propionate and 0.045% wt. tazarotene as claimed. However, the Examiner recognizes that it must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references, which make up the state of the art with regard to the claimed invention. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art.

(Id. at ¶ 37.) Note the last sentence, in which the Examiner explains that the test for obviousness does not require “that the claimed invention must be expressly suggested in any one . . . of the references,” but, instead, the test is “what the combined teachings of the references would have suggested.” The Examiner proceeded to explain how the combination of Gandhi, Angel, Bershad, and Jackson rendered the pending claims obvious, and concluded:

[O]ne of ordinary skill in the art of preparing a topical lotion and cream emulsions for treating psoriasis consisting of halobetasol propionate and tazarotene would have found it prima facie obvious to lower the concentration of tazarotene in the emulsion of Gandhi (0.05% wt.) to 0.045% wt. in view of Bershad in order to arrive at the instantly claimed emulsion.

(Id. at ¶ 42.)

The Examiner’s stated reasoning is quite relevant to Defendants’ argument about the Posting. As Bausch contends, the elements of the claimed invention taught by the Posting had already been found in the prior art by the Examiner, and the Examiner concluded that the prior art references in combination suggested the claimed invention. At most, the Posting could have provided a shortcut to the Examiner’s conclusion of obviousness, but it would not have changed that conclusion: the combined teachings of the prior art references suggested the claimed

invention.

On March 27, 2018, the applicants submitted amended claims and arguments responsive to the obviousness rejection in the office action of December 28, 2017. (Bruno Dec. Ex. 20.)

The applicants made a range of arguments, including a challenge to the Examiner's interpretation of the teachings of Bershad (*id.* at 8), and attempted to persuade the Examiner that the combined teachings of the prior art references do not suggest the inventive combination of 0.01% wt. HP and 0.045% wt. Taz. (*Id.* at 6-10.)

In the Office Action dated May 30, 2018, the Examiner issued a final rejection of all pending claims. (Bruno Dec. Ex. 21 at 1.) The Examiner acknowledged the arguments made by the applicants to overcome the prior obviousness rejection, but maintained and reiterated that rejection, rejecting the claims as obvious over the combination of Gandhi, Angel, Bershad, and Jackson. (*Id.* at ¶ 9.) As Bausch notes, the Examiner again stated that Gandhi taught the use of the combination of HP and Taz as a topical anti-psoriasis composition (*id.* at ¶ 13), that Angel disclosed the claimed concentration of halobetasol propionate (0.01%) (*id.* at ¶ 17), and that Bershad disclosed a range of tazarotene concentrations which encompassed the claimed concentration of tazarotene (0.045%) (*id.* at ¶ 21). The Examiner stated it would have been obvious to a skilled artisan to change the concentrations of the ingredients in the composition taught by Gandhi, based on the teachings of Angel and Bershad, to the concentrations in the claimed composition. (*Id.* at ¶¶ 23, 24, 26.) The Examiner next acknowledged the responsive arguments that the applicants submitted in order to overcome the described rejection, but stated that they were unpersuasive. (*Id.* at ¶¶ 33-42.) The Examiner concluded: "the claims fail to patentably distinguish over the state of the art as represented by obvious composition of the cited

references.” (Id. at ¶ 43.) The Examiner issued a final rejection of all pending claims as obvious. (Id.)

On August 8, 2018, the applicants submitted amended claims, changing claim 1 to add this language:

and wherein the composition comprising the halobetasol propionate and the tazarotene at said concentrations is capable of providing synergistic efficacy and synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging, for said treating.

(Bruno Dec. Ex. 22 at 3.) In the accompanying remarks, the applicants argued, in short, that the prior art references, separately or in combination, did not teach or suggest the claimed composition, wherein the composition provided synergistic efficacy and synergistic reduction, etc.⁹ (Id. at 6-9.)

On November 19, 2018, the PTO issued a Notice of Allowability for all pending claims. (Bruno Dec. Ex. 24 at 1.) It was accompanied by the Examiner’s statement of reasons for allowance. (Id. at 2-7.) Under the subheading of “Reasons for Allowance,” the Examiner wrote:

4. The following is an examiner's statement of reasons for allowance: At the time of the instant invention a topical composition for treating psoriasis comprising 0.01 % wt. halobetasol propionate, 0.045% wt. tazarotene, a dermatologically acceptable carrier; wherein the composition is an oil-in-water emulsion; wherein an oil phase in the oil-in-water emulsion comprises a liquid oil component; and wherein the liquid oil component is liquid at 22 °C and consists of diethyl sebacate and light mineral oil, said composition was not anticipated within the prior art. Additionally, there were no teachings or suggestions within the prior art that the combination of 0.01 % wt. halobetasol-propionate with 0.045% wt. tazarotene in the water in emulsion components above would result in providing synergistic efficacy and synergistic reduction of at least an adverse event selected

⁹ In this Opinion, the Court uses the expression, “synergistic reduction, etc.” as shorthand for the much longer claim phrase, “synergistic reduction of at least an adverse event selected from the group consisting of itching, burning, and stinging, for said treating.”

from the group consisting of itching, burning, and stinging, when applied to patients for treating psoriasis as found within Tables 8-12 of the instant specification and Affidavit of 08/09/2018. The closest prior art of record is documented below.

(Id. at ¶ 4.) The Examiner then discussed the prior art references, followed by this conclusion:

Accordingly, Applicants have identified a novel and non-obvious oil-in-water emulsion comprising halobetasol-propionate and tazarotene that yields a synergistic effect at reducing of at least an adverse event selected from the group consisting of itching, burning, and stinging in the psoriatic patient following topical administration, and therefore, claims 1, 8, 13-14 and 31-32 are allowed.

(Id. at ¶ 13.)

Defendants' materiality argument relies solely on the contents of the Posting and the contents of a small number of documents in the prosecution history. This Court finds that the cited documents in the prosecution history do not support Defendants' argument, for several reasons.

First, Padagis misunderstands the Examiner's reasons for allowance, as stated in the remarks accompanying the Notice of Allowability. Padagis states: "The Examiner's Reasons for Allowance for both patents further demonstrate the critical importance the Examiner placed on the claimed drug concentrations in allowing the claims." (Def.'s Opp. Br. at 32.) This statement is not supported by what the Examiner wrote in the cited document, nor by the events of the prosecution history. To the contrary, the prosecution history shows that the applicants never succeeded at persuading the Examiner that the combined prior art did not suggest the inventive combination of 0.01% wt. HP and 0.045% wt. Taz. Instead, it appears that, after the Examiner rejected their arguments at least twice, the applicants added new claim limitations to distinguish the prior art, as shown in the amendment to independent claim 1, submitted August 8, 2018. These new claim limitations, which applied to all claims, required both synergistic

efficacy and synergistic reduction, etc. It was only through the addition of those limitations that the applicants overcame the obviousness rejection and obtained a notice of allowance.

The first paragraph in the Examiner's statement of "reasons for allowance," numbered paragraph 4, contains two statements. The first statement says that the composition with the listed characteristics was not anticipated within the prior art. The second statement says that there were no suggestions within the prior art that the combination of 0.01% wt. HP and 0.045% wt. Taz would result in providing synergistic efficacy and synergistic reduction, etc. The concluding statement says that the inventors have identified a novel and non-obvious composition which produces the effect of synergistic reduction, etc. It is clear that the amendments to independent claim 1, filed August 8, 2018, which provided new and additional claim limitations, were crucial to overcoming the obviousness rejection.

Padagis has failed to persuade this Court that, had the Examiner known about the Posting, it would have changed the outcome, or changed any of the reasons for allowance. Padagis does not contend that the Posting would have anticipated any of the claims at issue. As already discussed, as to the obviousness analysis, the Examiner had already found the elements of the claimed invention taught by the Posting in other prior art references, and believed that a skilled artisan would have been motivated to combine them. Lastly, Padagis overlooks entirely the critical role of the limitation, "synergistic reduction, etc." The prosecution history shows that it was the addition of this limitation that played the critical role in overcoming the repeated obviousness rejections.

As Bausch contends, Padagis has failed to persuade that the Postings taught anything materially different from the prior art references discussed by the Examiner. The Examiner had

found references that taught the use of HP at .01% in a topical lotion to treat psoriasis (Angel), the use of Taz at .045% in a topical lotion to treat psoriasis (within the range of .025%-1% taught by Bershad), and the use of a combination of HP and Taz in a topical lotion to treat psoriasis (Gandhi). Padagis fails to recognize these fundamental facts. Nor does Padagis argue that there is a meaningful difference, in this case, between having these elements in three pieces of prior art rather than a single piece of prior art, the Posting. Padagis even had the opportunity, when the Court gave it leave to file a sur-reply, to respond to Bausch's argument to this effect on page 20 in its reply brief, but it did not do so.

Furthermore, Bausch argues persuasively, in reply, that the arguments Padagis offers in support of the Pillai Theory are inconsistent with the arguments offered in support of the Sugarman Theory, and that, in arguing for the Sugarman Theory, "Padagis repeatedly ties allowance to the patented invention's unexpected synergistic properties." (Pl.'s Reply Br. at 21.) The Court agrees that the inconsistency is striking, at least. Consider these statements from Defendants' Supplemental Statement of Facts (citations are omitted):

19. The Examiner allowed the claims of both of the Combination Patents directly following Bausch's addition of the synergy limitations and submission of Dr. Sugarman's declarations alleging unexpected results.

20. In allowing the claims of the Combination Patents, the Examiner focused on the synergy limitations and the alleged unexpected results, concluding that the prior art did not teach or suggest the claimed synergistic effects at the claimed concentrations of halobetasol propionate and tazarotene.

21. In allowing the claims of the Combination Patents, the Examiner repeatedly cited the Sugarman Declaration and the data in the specification that Dr. Sugarman and Dr. Vo identified as support for the claimed synergistic effects.

22. The Examiner allowed the claims of the Combination Patents as a direct result of the affirmative representations by Dr. Sugarman that the claimed synergistic effects would have been unexpected to a skilled artisan.

These factual assertions are fully consistent with Bausch's understanding of the prosecution history, and inconsistent with the view of the prosecution history espoused by Padagis when arguing in support of the Pillai Theory. At a minimum, these statements point to evidence that supports Plaintiff's arguments against the Pillai Theory, rather than Defendants' arguments in support of it.

Similarly, when discussing the Sugarman Theory, Defendants' opposition brief presents a summary of the prosecution history of the Combination Patents that is consistent with Plaintiff's case against the Pillai Theory, not Defendants' case in support:

During prosecution of the Combination Patents, Bausch added the limitations requiring "synergistic efficacy and synergistic reduction of at least an adverse event . . ." to obtain allowance of the claims in response to the Examiner's rejection of the pending claims as obvious over the prior art. Padagis SMF ¶ 10. Bausch's prosecution attorney, Toan Vo, Ph.D., argued that the amended claims were not obvious because the recited synergistic efficacy and synergistic reduction of adverse events would have been "unexpected and surprising." Padagis SMF ¶ 11.

...

The Examiner allowed the claims of both the '895 and the '787 patents directly following Bausch's addition of the synergy limitations and submission of Dr. Sugarman's declarations alleging unexpected results. Padagis SMF ¶ 19. In allowing the claims, the Examiner focused on the synergy limitations and the allegedly unexpected results, concluding that the prior art did not teach or suggest the claimed synergistic effects at the claimed concentrations of halobetasol propionate and tazarotene. Padagis SMF ¶ 20

(Def.'s Opp. Br. at 6, 8.) This is what Bausch contends, and it comes very close to being a concession from Defendants that Bausch's understanding of the reasons for allowance of the Combination Patents is correct.

Padagis argues that the instant case is "similar" to Belcher Pharms., LLC v. Hospira, Inc., 11 F.4th 1345 (Fed. Cir. 2021). (Def.'s Opp. Br. at 32.) While there are certain factual

similarities – notably, a question about a range disclosed in the prior art – Padagis does not even argue that Belcher stands for any legal proposition that helps Padagis establish the materiality of the Posting. Id. at 1353. Belcher does not abrogate or conflict with the teachings of Regeneron. The materiality inquiry is focused on the perspective of the Examiner, not of the applicants:

Determining but-for materiality requires that the court place itself in the shoes of a patent examiner and determine whether, had the reference(s) been before the examiner at the time, the claims of the patent would have still issued. . . . [T]he court must determine whether a reasonable patent examiner would have allowed the claims had she known of the Withheld References.

Regeneron, 864 F.3d at 1351. Applicants may make many arguments during prosecution; some may have merit and some may not. Padagis has offered no evidence that the Examiner was ever persuaded that the invention’s specific concentrations of HP and Taz were non-obvious, nor has Padagis argued that a reasonable patent examiner would have believed so.

As to the Pillai Theory, Padagis has failed to offer evidence sufficient to persuade a reasonable factfinder of the materiality of the Posting. As to the Pillai Theory, Padagis has failed to satisfy its burden of proof as to an essential element of its inequitable conduct case. As to the Sugarman Theory, Padagis failed to offer evidence sufficient to persuade a reasonable factfinder of the material falseness of the Sugarman Declaration, as well as an intent to deceive the PTO on the part of Sugarman or the applicants. As to the Sugarman Theory, Padagis has failed to satisfy its burden of proof as to two essential elements of its inequitable conduct case.

The Supreme Court held in Celotex:

In such a situation, there can be “no genuine issue as to any material fact,” since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial. The moving party is “entitled to a judgment as a matter of law” because the nonmoving party has

failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.

Celotex, 477 U.S. at 322-23. This Court finds that there has been a complete failure of proof concerning essential elements of Defendants' inequitable conduct case, both as to the Pillai Theory and the Sugarman Theory. Padagis has failed to defeat Bausch's motion for summary judgment of no inequitable conduct, which will be granted.

For these reasons,

IT IS on this 20th day of May, 2022

ORDERED that Plaintiff's motion for summary judgment of no inequitable conduct (Docket Entry No. 101) is **GRANTED**, and Judgment is entered in Plaintiff's favor on Defendants' affirmative defense and counterclaim that the Combination Patents are unenforceable due to inequitable conduct.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.